UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,548	05/26/2000	Alan H. Lazarus	701826/50750	7491

7590 11/18/2002

David S Resnick
Nixon Peabody LLP
101 Federal Street
Boston, MA 02110

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/18/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/579,548	Applicant(s) LAZARUS
	Examiner GAMBEL	Art Unit 644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 8/27/01

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 24-33

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 31-33

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 24-30

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☑ All b)☐ Some * c)☐ None of:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

Paper no 17

DETAILED ACTION

1. Applicant's election of Group I and the species ITP (claims 24-30) in Paper No. 16 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 31-33 have been withdrawn as being drawn to the non-elected invention.

2. The drawings, filed 5/26/00 comply with 37 CFR 1.84.

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 24-30 are rejected under 35 U.S.C. § 102(e) as being anticipated by Armitage et al. (U.S. Patent No. 6,264,951 (see entire document, including Detailed Description of the Invention).

Armitage et al. teach methods of inhibiting CD40L binding to CD40 with soluble monomeric CD40L for the treating of allergies, graft-versus-host-disease and autoimmune diseases such as SLE, rheumaotid arthritis and diabetes (see entire document, including column 10, paragraphs 2-3 and column 21, paragraph 1 and Claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations of inhibiting an anti-HLA alloimmune response would be inherent properties of the referenced methods to inhibit the above-mentioned diseases with soluble monomeric CD40L. The claimed SEQ ID NO: 1 is the same sequence of the prior art CD40L (e.g. see SEQ ID NO: 12 of Armitage).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

It is noted the elected invention is drawn to methods of treating ITP. Given the application of Armitage et al. (U.S. Patent No. 6,264,951) in the rejection under 35 USC 103(a) herein, Armitage et al. has been applied as art under 35 USC 102(e) given the breadth of the instant claims.

9. Claims 24-30 are rejected under 35 U.S.C. § 102(e) as being anticipated by Aruffo et al. (U.S. Patent No. 6,376,459 (see entire document, including Detailed Description of the Invention; also see columns 15-17).

Aruffo et al. teach methods of inhibiting CD40CR (i.e. CD40L) binding to CD40 with soluble monomeric CD40L for the treating of allergies, graft-versus-host-disease and autoimmune diseases such as SLE, rheumaotid arthritis and Sjogren's syndrome (see entire document, including Detailed Description of the Invention; also see columns 15-17). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations of inhibiting an anti-HLA alloimmune response would be inherent properties of the referenced methods to inhibit the above-mentioned diseases with soluble (CD40CR) (i.e. CD40L). The claimed SEQ ID NO: 1 is the same sequence of the prior art CD40L (e.g. see SEQ ID NO: 2 of Aruffo).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

It is noted the elected invention is drawn to methods of treating ITP. Given the application of Aruffo et al. (U.S. Patent No. 6,376,459) in the rejection under 35 USC 103(a) herein, Armitage et al. has been applied as art under 35 USC 102(e) given the breadth of the instant claims.

10. Claims 24-30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over de Armitage et al. (U.S. Patent No. 6,264,951 AND/OR Aruffo et al. (U.S. Patent No. 6,376,459) in view of Black et al. (U.S. Patent No. 6,440,418) wherein ITP was known to be associated with difficulties associated with alloimmune responses, as evidenced by Harrington et al. (Vox San 51: Suppl. 2: 18-21, 1986)

Armitage et al. and Aruffo et al. are taught above and differ from not disclosing the autoimmune disease ITP as a targeted disease per se.

In teaching the use of blocking CD40:gp39 (i.e.CD40L) interactions with anti-gp39 (i.e. anti-CD40L) antibodies (see Detailed Description of the Invention), Black et al. Is useful for the treatment of allergies and autoimmune disorders, including rheumatoid arthritis, multiple sclerosis, diabetes, SLE and ITP (see column 10, lines 25-39).

Given the common teachings among Armitage et al., Aruffo et al. and Black et al. to treat a number of autoimmune diseases by blocking the CD40:CD40L pathway, one of ordinary skill in the art would have been motivated to target other autoimmune diseases dependent on T cell help such as ITP with soluble CD40L, as taught by Armitage et al. and Aruffo et al. Given the common properties of antagonizing the CD40:CD40L pathway in a number of autoimmune diseases as well as GVHD, as taught by Armitage et al., Aruffo et al. and Black et al., the ordinary artisan would have had an expectation of success that soluble CD40L antagonists would have inhibited a number of conditions associated with T cell help and antigen presentation, including ITP, as taught by Black et al.

In addition, the claimed functional limitations of inhibiting an anti-HLA alloimmune response would be inherent properties of the referenced methods to treat ITP, wherein ITP was known to be associated with difficulties associated with alloimmune responses, as evidenced by Harrington (see entire document). Also it is noted that the uses of known immunosuppressives such as glucocorticoids were effective in retarding antibody synthesis (see Methods of Treating ITP, including Table 1).

In addition to the combination of Armitage et al., Aruffo et al. and Black et al. to inhibit immune responses including ITP by blocking the CD40:CD40L pathway, one of ordinary skill in the art would have been further motivated to provide less toxic and more specific methods of immunosuppressives relying upon the CD40:CD40L pathway to inhibit humoral immune responses and antigen presentation to treat ITP, rather than relying upon the expensive or toxic immunosuppressive methods practiced in the art.

Therefore, one of ordinary skill in the art would have been motivated to provide immunosuppression via blocking the CD40:CD40L pathway with soluble CD40L to block T cell help and antigen presentation in order to treat ITP with an expectation of success that such treatment would inhibit the alloimmune response associated with the multiple platelet transfusions experienced by said ITP patients, give the teachings above. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
November 18, 2002